

October 24, 2005

Donald W. Jehn  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike  
Rockville, MD 20852

Dear Mr. Jehn:

The purpose of this letter is to provide comments to aid in your deliberations regarding an over-the-counter (OTC) rapid HIV screening test.

Rapid HIV testing has had a significant and positive impact in the State of Michigan. The Michigan Department of Community Health (MDCH) was among the early adopters of rapid HIV testing because we recognized the significant public health value of this technology. This technology has allowed us to increase testing in settings serving high-risk populations such as hospital emergency departments, community health clinics, substance abuse treatment facilities and county correctional facilities. We also support HIV testing using rapid screening test technologies in mobile health clinics and other community-based organizations.

Our experience indicates that rapid HIV screening tests are a valuable tool for HIV prevention in public health settings. However, we believe that there are several issues associated with making this technology available OTC which warrant serious consideration.

- (1) How can linkage to medical services best be accomplished in conjunction with an OTC rapid HIV screening test? Linkage to medical services is a key component of HIV testing services in public health settings. In order for individuals to obtain the full benefit of medical treatment for HIV disease, it is critical that they be effectively linked with such resources.
- (2) How can linkage to prevention and support services best be accomplished in conjunction with an OTC rapid HIV screening test? HIV testing services provided in public health settings also emphasize provision of prevention services. In particular, skilled counselors provide basic psychosocial support to clients upon receipt of test results. Clients in need are provided with assistance with accessing crisis intervention services.

- (3) How would an OTC rapid HIV screening test impact HIV risk behavior? Clients that receive HIV testing in public health settings are provided with information about the meaning of test results, particularly as they relate to recent exposure and ongoing risk behaviors. This assists these clients in adopting behaviors to protect partners from becoming infected. It is essential that individuals using OTC rapid HIV screening tests be provided with this information in clear and simple language to ensure that they accurately understand test results and take appropriate prevention measures.
- (4) What mechanisms will be required to prevent bulk sales of OTC rapid HIV screening tests? Michigan's public health code regulates who can conduct HIV testing. MDCH carefully monitors publicly supported HIV test sites to ensure the quality of services provided. To ensure that high quality testing is provided and to protect the health of our citizens, it is essential that mechanisms be established to prevent bulk sales of OCT rapid HIV screening tests.

We thank you for the opportunity to provide you with these comments. If you have questions about these issues, please contact Loretta Davis-Satterla, Director, Division of Health, Wellness and Disease Control at (517) 241-5900.

Sincerely,

Loretta Davis-Satterla, MSA  
Director, Division of Health, Wellness and Disease Control